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Sir:

Enclosed for filing is a complete patent application, entitled "PHYSIOLOGICAL DATA INTERPRETATION SYSTEM" invented by:

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and including the following documents:

Specification including Claims - 13 pages
Abstract of the Disclosure
Drawings - 6 sheets
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Date: 10/6/2000
cc: Docketing
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PHYSIOLOGICAL DATA INTERPRETATION SYSTEM

BACKGROUND OF THE INVENTION

Physiological activity is monitored in the diagnosis and treatment of numerous diseases and medical conditions. For example, heart activity is commonly monitored by collecting electrocardiogram ("ECG") data. ECG data is typically interpreted by an electrocardiographer, a physician specially trained in reading the waveforms created by ECG equipment.

In many situations, ECG and other physiological data is available, but an expert suitably trained in reading that data is not. In response to this problem, software interpretation tools have been developed to aid the non-expert physician in interpreting and using such data. However, these tools, particularly ECG tools, are not satisfactory. Existing ECG tools are designed to generate an interpretation. The computer-generated interpretation is supported by one or more statements that describe the criteria that the computer uses to reach its conclusion. However, these statements are typically limited to describing the character of the waveform, which is usually of little assistance to the novice ECG reader. Another shortcoming of existing tools is that they generate conclusions based on the assumption that the ECG device correctly measured the ECG. In other words, existing computer tools assume that no faults or other errors ever occur in ECG measuring equipment.

The output from an existing ECG interpretation system is shown in FIG. 1. The output includes a screen image 10. The image 10 includes patient identifying information 12, initial diagnostic information 14, such as a complaint or symptom, vital signs data 16, physiological data in the form of waveforms 18, waveform characteristic information 20, a diagnosis or interpretation 22, and a group of reason statements 24. In the example, shown, the interpretation 22 indicates that there is a 42% probability that the patient has acute cardiac ischemia. The reasons supporting the interpretation are set out in the reason statements 24. For example, the interpretation is based on the fact that the patient is male, complaining of chest pain,

and that "no significant Q waves or primary ST segment abnormalities" were detected. The reason statements 24 also indicate that the "[a]nterior T waves" are flat.

Most non-specialists find reason statements such as those shown in FIG. 1 to be too technical and, therefore, unhelpful in understanding the interpretation. Further, non-specialists are generally uncomfortable relying on an interpretation lacking a high probability. In the example shown, the interpretation generated has a probability of only 42%, meaning that there is a 58% chance that another interpretation is appropriate for the data. Thus, in those cases where present systems generate an interpretation of low probability, they are often of little help.

SUMMARY OF THE INVENTION

Accordingly, it would be desirable to have an improved system for interpreting ECG and other physiological data records.

The invention provides real-time decision support in the interpretation of physiological data. The invention includes a system having a library of physiological data records, and a physiological data acquisition device that is coupled to the library and capable of acquiring physiological data from a patient or subject. The library may be stored on a remote server or on hardware local to the acquisition device. The acquisition device includes an interpretation module to generate an interpretation of the physiological data and a correlation module to compare the interpretation to the records in the library of physiological records and determine a set of correlated data records. The system also includes an output device coupled to the acquisition device to display the interpretation and the correlated data records. In this manner, the user may compare the present data to previous, expertly interpreted data records. This comparison acts as an aid in interpreting the data.

Preferably, the system includes an expert location coupled to the acquisition device. The user of the system may send questions and other messages regarding the interpretation to the expert location via devices such as email, instant messaging, and chat services. An expert in the medical field relevant to the physiological data being

interpreted may then respond to the messages received at the location, to provide substantially real-time assistance to the user of the acquisition device.

The invention provides a new method of interpreting physiological data. The method includes establishing a library of interpreted physiological data records, gathering the physiological data from a patient or subject, interpreting the physiological data based on a predetermined set of criteria to generate an interpretation, correlating the interpretation to one or more of the physiological data records in the library of physiological data records, and displaying the interpretation and the correlated physiological data records on a display. The method provides information unavailable in present systems, which typically only provide an interpretation of the data and abstract reasons supporting the interpretation, rather than clinical examples of medical conditions as provided with the correlated data records.

Additional assistance in interpreting the physiological data from the subject may be gained by establishing a communications link to an expert location, transmitting information concerning the interpretation to the expert location, and displaying a communication from the expert location on the display in response to the transmission. Typically, information is transmitted to the expert location in the form of a text message. However, voice-based chat services, instant messaging, and the like may be used to communicate with the expert location.

Another feature of the invention provides even more assistance to the user in interpreting physiological data. If desired, the invention may be configured such that the acquisition device is linked to a library of supplemental materials. After an interpretation is generated, links may be generated to the relevant records in the library of supplemental materials and the user may use those links to access the material to gain additional details and information concerning diagnosis, treatment, and the like for the condition indicated by the interpretation.

In order to enhance the accuracy of the interpretation provided by the invention, the integrity of the physiological data from the patient may be checked. This involves extracting one or more patterns from the physiological data, and

comparing the extracted patterns from the physiological data to a set of known patterns. If discrepancies are noted, malfunction in the system in indicated.

As is apparent from the above, it is an advantage of the present invention to provide a method and system of interpreting and aiding in the interpretation of physiological data. Other features and advantages of the present invention will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG.1 is an illustration of output from a prior-art physiological data interpretation system.

FIG. 2 is an illustration of a physiological interpretation system of the invention.

FIG. 3 is an illustration of output from the system of FIG. 2.

FIG. 4 is an illustration of output from the system of FIG. 2.

FIG. 5 is an illustration of measurements of physiological waveforms that are used to define features.

FIG. 6 is an illustration of a communication from an expert.

DETAILED DESCRIPTION

Before one embodiment of the invention is explained in detail, it is to be understood that the invention is not limited in its application to the details of the construction and the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced or being carried out in various ways. Also, it is

to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting.

A physiological data system 30 is shown in FIG. 2. Before discussing the rest of the system 30, it should be understood that the invention will be described with respect to ECG data. However, the system could be configured to aid in the interpretation of other data such as image data, including x-ray images, nuclear images, ultrasonic images, and magnetic resonance; blood pressure; oxygenation; brain activity; etc. Thus, the invention should not be limited to the examples described and shown.

The system includes a number of sensors or similar devices 32 attached to a patient 34. Physiological data sensed by the sensors 32 is transmitted over a link 36 to an acquisition and display unit 38 having a main unit 40 and a display 42. The main unit 40 includes typical hardware such as a processor 44, an input/output interface 46, and data storage or memory 48. The main unit also includes an operating system 50 and other software in the form of a display module 52, an optional browser 54, such as a web browser, a correlation module 56, which may include an optional data integrity checking module (not shown), and an interpretation module 58.

The acquisition and display unit 38 performs several functions. It acquires signals or raw data from the patient 34 using the sensors 32. The raw data is then measured. For example, and as shown in FIG. 5, when ECG data is acquired, numerous characteristics such waveform height, distance between peaks, etc. are measured. Once the measurements are made, various features of the waveform are extracted. As will be discussed further below, these features can then be compared to the features of previously interpreted physiological data and used to check the interpretation made by the interpretation module 58.

The interpretation module 58 uses the measured features to generate an interpretation of the physiological data. A variety of existing physiological interpretation modules may be used in the invention. When configured to interpret

ECG data, 12SL™ software available from GE Medical Systems Information Technologies, Inc. may be used in the invention.

The acquisition and display unit 38 may include an optional communication module 60 to coordinate and control communications with an expert location (discussed below) and remote libraries of data (also discussed below). Communications between the acquisition and display unit 38 and remote devices may be enhanced with an information filter 62 coupled or made a part of the communication module 60. The information filter 62 may be configured to block the transmission of predetermined information, such as personal or private patient information, to ensure that the predetermined information is not transmitted to devices and locations coupled to the acquisition and display unit 38.

As noted, the interpretation module 58 analyzes and interprets the data or data set acquired from the patient 34, and generates an interpretation for that data set. The correlation module then links the interpretation to physiological records that have the same or similar features and interpretation. For example, an anterior myocardial infarction (MI) that was elicited due to a poor R wave progression would be linked to ECGs with the same feature, as opposed to all ECGs that exhibit features that are possible with anterior MI.

The correlation module 56 links the interpretation to records in a library of physiological data records 70. Specifically, the correlation module 56 matches or correlates features extracted from the current physiological data to features in the previously interpreted records of physiological data stored in the library 70. The correlation module then creates links, such as hyperlinks to the correlating records. The library of physiological data records 70 is coupled to the acquisition and display unit 38 via a communication link 72. The communication link may be a local bus when the library of records 70 is stored in local storage or may be a variety of other links, including an Internet link, such that the library of records 70 may be stored on a remote server 74, which may be a web server. The server 74 may also include a library of additional or supplemental educational materials or information records 76 that can be linked to the displayed physiological data and correlated records to

provide explanations of relevant features and characteristics of the data and interpretation. Locating the records 70 and 76 on a server has several advantages including the ability to maintain a central, easily updated depository of information. However, the records 70 and 76 could be maintained on separate severs or locally on the data acquisition and display unit 38.

The data and acquisition unit 38 may also be linked to an expert location 80 via a link 82. The expert location may be a customized web site or portal and the link 82 may be an Internet link. However a variety of locations and communication links could be used. For example, a remote sever with a dial-up link could be used in the invention. Communications between the expert location and the data acquisition and display unit 38 may take place using text or voice-based electronic mail, instant messaging, or chat services. Such services are particularly suitable when the data acquisition and display unit 38 is configured such that the display module 52 directs physiological data images to be displayed in a window generated by the browser 54 and the expert location is coupled to the unit 38 via an Internet connection.

The expert location 80 is a site or similar locale with a computer or similar appliance. Typical examples include a computer at an office or facility of an expert in the medical area relevant to the type of physiological data being interpreted by the interpretation module 58. Messages from the data acquisition unit 38 are received at the expert location 80 and responded to by the expert to assist the physician or other individual using the unit 38 to interpret the physiological data.

FIG. 3 illustrates physiological data in the form of an ECG 100. The ECG 100 includes three waveforms 102, 104, and 106. The ECG 100 also includes patient ECG identifying information 107, patient identifying information 108, vital signs data 110, and an interpretation 112. The interpretation 112 is generated by the interpretation module 58. Once the interpretation is generated, the correlation module reviews the library of records 70, determines matching physiological records, and links those matching records to the ECG record 100. The system 30 can be configured such that the selection of icon or button 116 in the browser 54 causes the display of the matching records.

FIG. 4 shows a screen 118 including the ECG 100 with matching records 122, 122, and 124. The screen 118 also includes an explanatory statement 128 describing a pertinent characteristic of the waveform 106.

In addition to providing an interpretation and supplemental information in the form of matching physiological records and explanatory statements, the invention may provide integrity checking. Specifically, the data acquisition and display unit may include an integrity checking module that ensures that the measurements made by the data acquisition and display unit are not biased or erroneous due to faults or other problems in the unit 38. The integrity checking module matches patterns in the features of the present physiological data to the features in the physiological data records correlated by the correlation module. When a deviation is detected, an erroneous measurement has been made.

As noted above, if a system user desires additional information concerning the interpretation of the physiological data, he or she may obtain expert advice by communicating with an expert at the expert location. FIG. 6 shows an exemplary expert response screen 150 that may be displayed on the acquisition and display unit 38. The screen includes the ECG 100 with an expert commentary 160 that may be generated using one of the communication tools noted above. The expert response screen 150 may also include expert identifying information 162 such as the name and picture of the expert providing the commentary.

As can be seen from the above, the invention provides a method and system for interpreting physiological data and of providing real-time assistance in interpreting such data.

Various features and advantages of the invention are set forth in the following claims.

CLAIMS

What is claimed is:

1. A method of providing real-time decision support in the review of physiological data, the method comprising:

establishing a library of interpreted physiological data records;

gathering the physiological data;

interpreting the physiological data based on a predetermined set of criteria to generate an interpretation;

correlating the interpretation to one or more of the physiological data records in the library of physiological data records; and

displaying the interpretation and the correlated physiological data records on a display.

2. A method as claimed in claim 1, further comprising:

establishing a communications link to an expert location;

transmitting information concerning the interpretation to the expert location; and

displaying a communication from the expert location on the display.

3. A method as claimed in claim 2, wherein transmitting information concerning the interpretation includes transmitting a text message.

4. A method as claimed in claim 2, wherein transmitting information concerning the interpretation includes transmitting a voice message.

5. A method as claimed in claim 1, further comprising:

extracting one or more patterns from the physiological data; and

comparing the extracted patterns from the physiological data to a set of known patterns.

6. A method as claimed in claim 5, further comprising determining whether the extracted patterns match one or more patterns in the set of known patterns.

7. A method as claimed in claim 1, further comprising:

creating a library of education materials; and

displaying some of the education materials on the display.

8. A method as claimed in claim 1, further comprising displaying a message based on the interpretation on the display.

9. A method as claimed in claim 1, further comprising displaying the physiological data on the display.

10. A physiological data interpretation system comprising:

a library of physiological data records;

a physiological data acquisition device capable of acquiring physiological data and coupled to the library of physiological data records, the acquisition device having an interpretation module to generate an interpretation of the physiological data and a correlation module to compare the interpretation to the records in the library of physiological records and determine a set of correlated data records; and

an output device coupled to the acquisition device.

11. A system as claimed in claim 10, wherein the output device is a display.

12. A system as claimed in claim 10, further comprising

an expert location coupled to the acquisition device.

13. A system as claimed in claim 12, wherein the expert location is a portal.

14. A system as claimed in claim 12, wherein the acquisition device includes an information filter.

15. A system as claimed in claim 12, wherein the acquisition device includes a communications module capable of transmitting messages to and receiving messages from the expert location.

16. A system as claimed in claim 15, wherein the messages include text information.

17. A system as claimed in claim 15, wherein the messages include voice information.

18. A system as claimed in claim 10, further comprising a server coupled to the acquisition device, and wherein the library of physiological records is located on the server.

19. A system as claimed in claim 10, further comprising a library of supplemental materials coupled to the acquisition device.

20. A system as claimed in claim 10, wherein the library of physiological data records includes ECG data.

21. A system as claimed in claim 10, wherein the acquisition device is an ECG acquisition device.

22. A system as claimed in claim 10, wherein the acquisition device includes a browser.

23. A system as claimed in claim 10, wherein the interpretation includes at least one textual message.

24. A system as claimed in claim 10, wherein the acquisition module includes a confirmation module to confirm the integrity of the physiological data.

25. A method of interpreting physiological data, the method comprising:

acquiring physiological data;

interpreting the physiological data based on a predetermined set of criteria to generate an interpretation;

correlating the interpretation to one or more physiological data records in a library of physiological data records; and

displaying the interpretation and the correlated physiological data records on a display.

26. A method as claimed in claim 25, further comprising:

establishing a library of interpreted physiological data records.

27. A method as claimed in claim 25, further comprising:

establishing a communications link to an expert location;

transmitting information concerning the interpretation to the expert location; and

displaying a communication from the expert location on the display.

28. A method as claimed in claim 27, wherein transmitting information concerning the interpretation includes transmitting a text message via instant messaging.

29. A method as claimed in claim 27, wherein transmitting information concerning the interpretation includes transmitting a voice message via voice-based instant messaging.

30. A method as claimed in claim 25, further comprising:

checking the integrity of the acquired physiological data by extracting one or more patterns from the physiological data; and

comparing the extracted patterns from the physiological data to a set of known patterns.

31. A method as claimed in claim 25, further comprising:

creating a library of supplemental materials; and

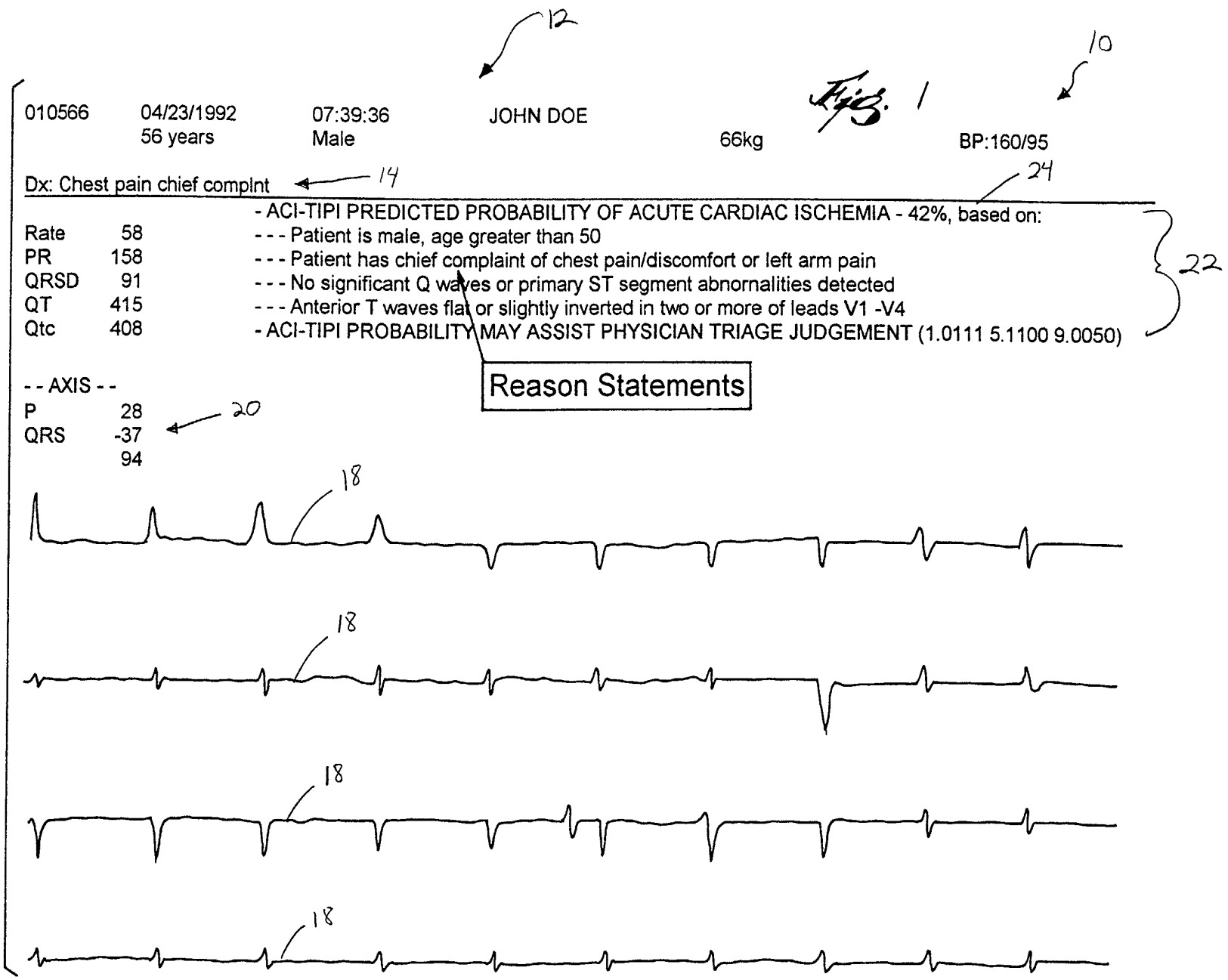
displaying some of the supplemental materials on the display.

ABSTRACT

A method and system for interpreting physiological data. The system includes a library of physiological data records, and a physiological data acquisition device that is coupled to the library and capable of acquiring physiological data from a patient or subject. The library may be stored on a remote server or on hardware local the acquisition device. The acquisition device includes an interpretation module to generate an interpretation of the physiological data and a correlation module to compare the interpretation to the records in the library of physiological records and determine a set of correlated data records. The system also includes an output device coupled to the acquisition device to display the interpretation and the correlated data records. Preferably, the system includes an expert location coupled to the acquisition device. The user of the system may send questions and other messages regarding the interpretation to the expert location via devices such as email, instant messaging, and chat services. An expert in the medical field relevant to the physiological data being interpreted may then respond to the messages received at the location to provide substantially real-time assistance to the user of the acquisition device.

The invention provides a method of interpreting physiological data that includes establishing a library of interpreted physiological data records, gathering the physiological data from a patient or subject, interpreting the physiological data based on a predetermined set of criteria to generate an interpretation, correlating the interpretation to one or more of the physiological data records in the library of physiological data records, and displaying the interpretation and the correlated physiological data records on a display.

09907 "4904960



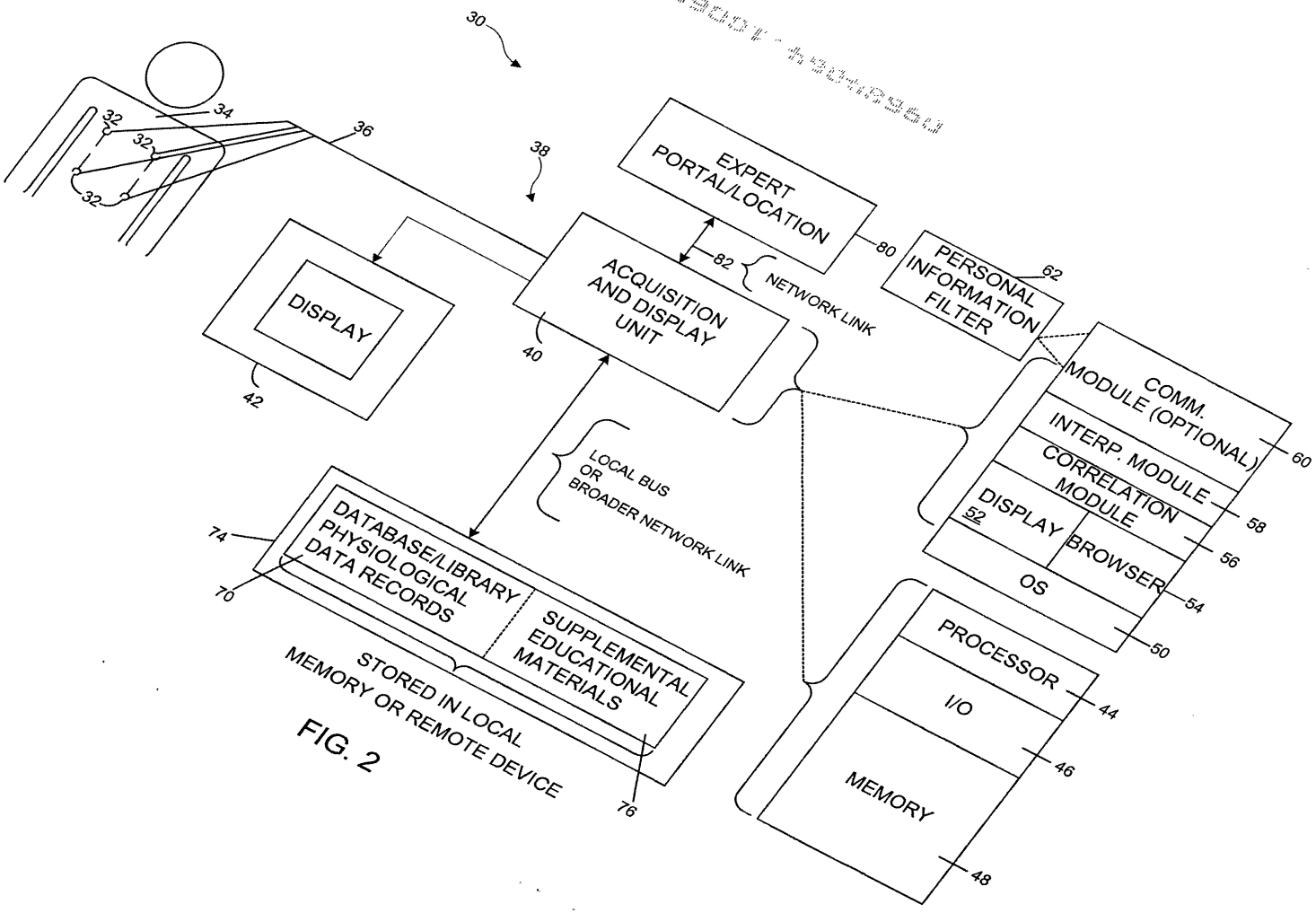

30
34
32
32
32
36
38
EXPERT PORTAL/LOCATION
80
82
NETWORK LINK
PERSONAL INFORMATION FILTER
62
DISPLAY
42
ACQUISITION AND DISPLAY UNIT
40
COMM. MODULE (OPTIONAL)
60
INTERP. MODULE
CORRELATION MODULE
58
DISPLAY
52
BROWSER
56
OS
54
50
LOCAL BUS OR BROADER NETWORK LINK
74
70
DATABASE/LIBRARY PHYSIOLOGICAL DATA RECORDS
SUPPLEMENTAL EDUCATIONAL MATERIALS
STORED IN LOCAL MEMORY OR REMOTE DEVICE
76
PROCESSOR
44
I/O
46
MEMORY
48

FIG. 2

09907 "490+8960

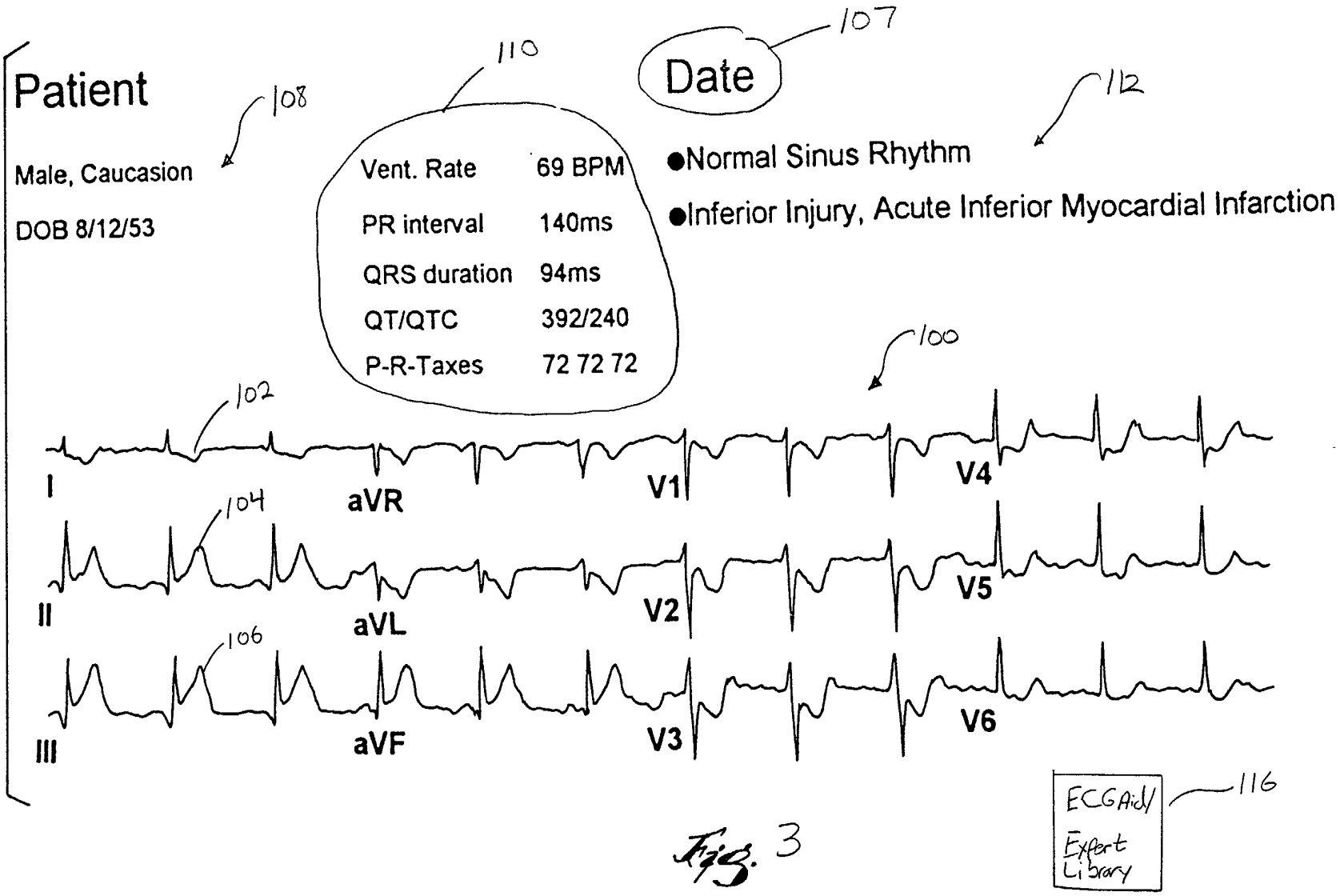


Fig. 3

09907 "4904,9960

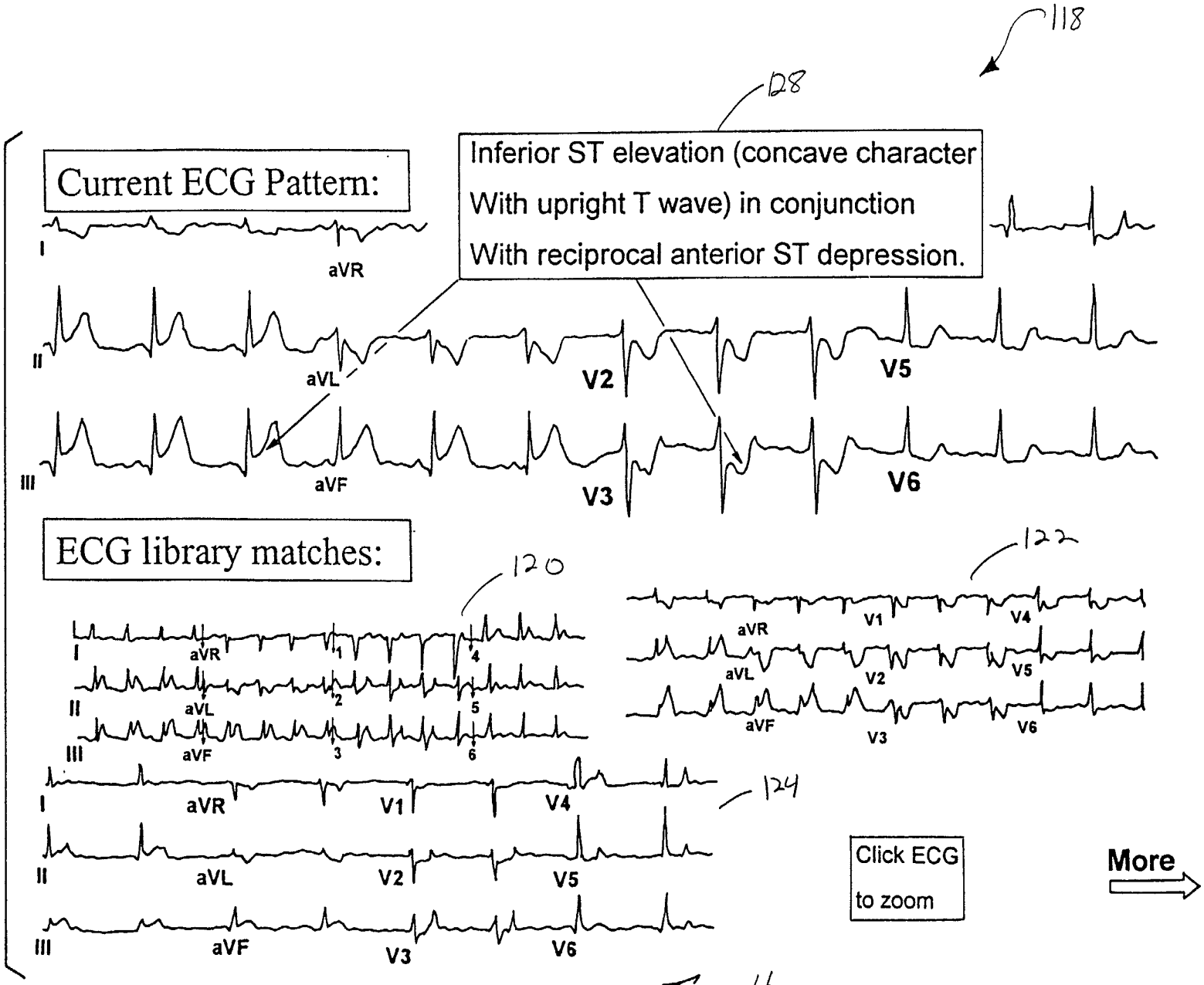


Fig. 4

DOSOOT' 4904,8960

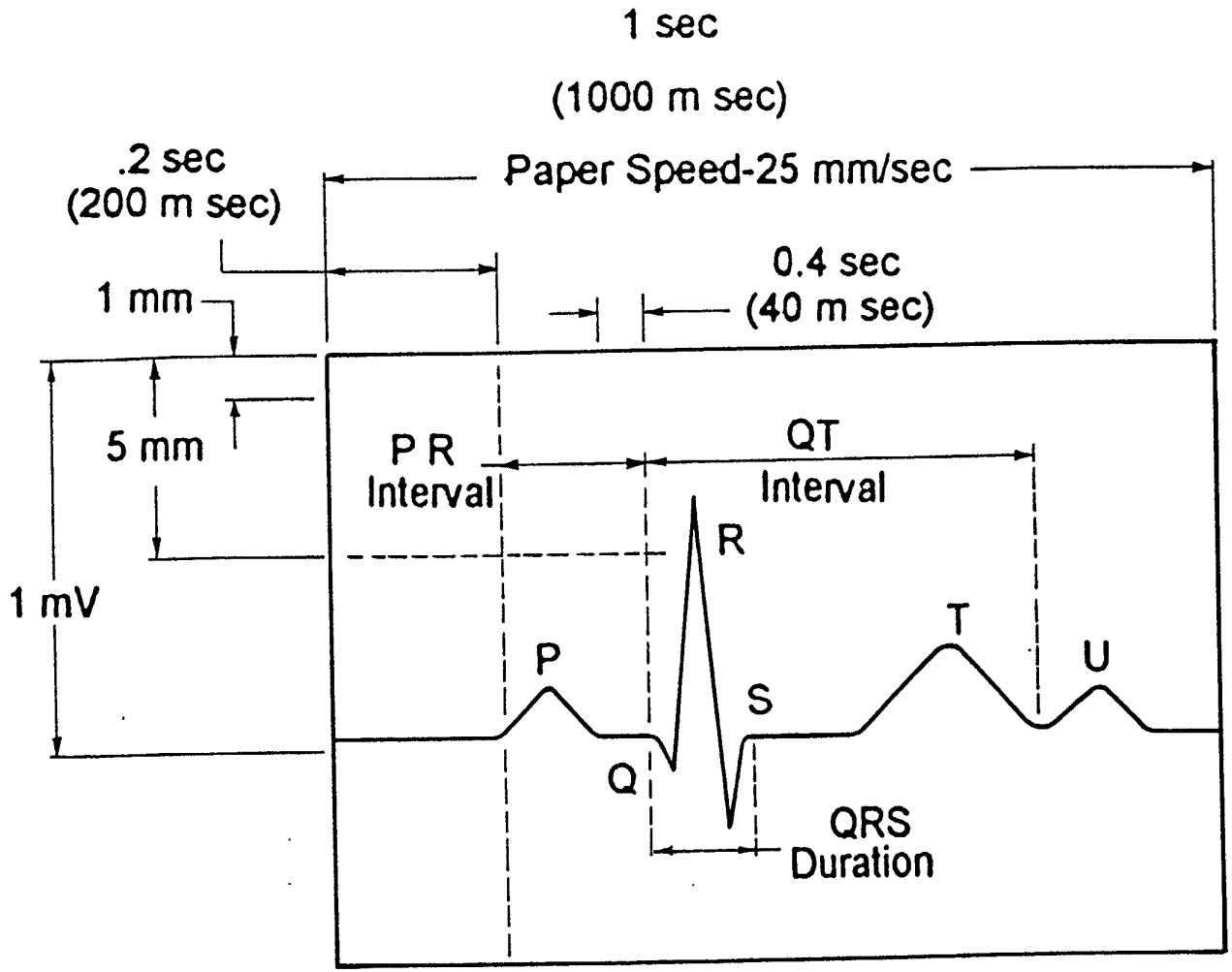
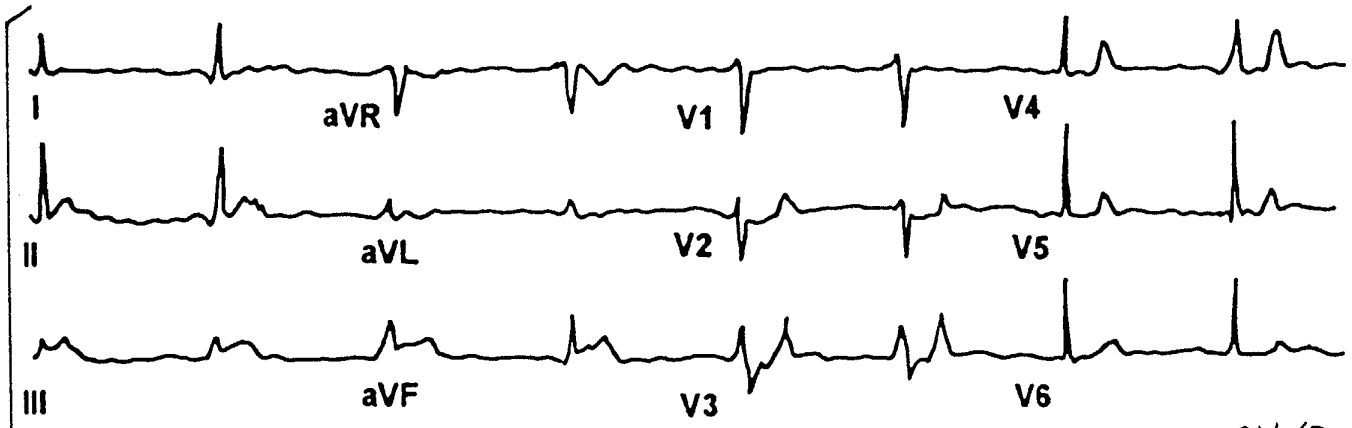


Fig. 5

150



100

160

"Although the ST/T contour in the inferior leads is concave this is a highly specific pattern of acute inferior myocardial infarction. Note the abnormal ST depression in V3. This coupled with the ST elevation in lead II, indicates acute inferior MI. The specificity for this call is 99%."

162

Dr. Expert

Community Medical Center

Fig. 6